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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,996	05/24/2007	Mariko Fujimura	0152-0842PUS1	2104
2292 7590 10/27/2010 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			EXAMINER DO, PENSEE T	
			ART UNIT 1641	PAPER NUMBER
			NOTIFICATION DATE 10/27/2010	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/587,996	Applicant(s) FUJIMURA ET AL.	
	Examiner Pensee T. Do	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/20/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Finality Withdrawn

Applicants have requested to withdraw the finality of the last office action sent on June 22, 2010 due to the addition of new claims 9-11 on the amendment dated December 1, 2009. This is found persuasive. Therefore, the finality of the last office action is vacated and this office action is a final office action.

Priority

This application, 10587996, filed 05/24/2007 is a national stage entry of PCT/JP05/01504 , International Filing Date: 02/02/2005 and claims foreign priority to 2004-026237 , filed 02/03/2004 and has a publication number of 20080131978. The effective filing date is 2/03/2004.

Amendment Entry & Claims Status

The amendment filed on September 20, 2010 has been acknowledged and entered.

Claims 1, 4-8 and newly added claim 9 and 10 are pending and being examined.

Information Disclosure Statement

The IDS submitted on September 20, 2010 has been acknowledged and considered.

Withdrawn Rejection(s)

Rejection under 112, 1st paragraph in the previous office action is withdrawn herein due to the deletion of "without stirring" on the amendment filed September 20, 2010.

Claimed Invention

1. (Currently Amended) A labeled specific binding material comprising a substance capable of specifically binding to an analyte, a spacer and a magnetic bead having a diameter of 0.5 to 10 μm , wherein the specific binding substance is coupled to the magnetic bead via the spacer and the spacer is polyalkylene glycol having 50 to 500 repeat units.

Maintained Rejection(s)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6, 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Josephson et al. (US PGPub. 2003/0092029 A1) in view of Rohr (US 5,445,970) and further in view of Thompson (US PGPub 2003/0190304).

For claim 1, Josephson teaches a composition comprising binding moieties linked to a magnetic particle. The binding moieties cause a specific interaction with a target molecule (see [58]) via functionalized polymer such as polyethylene glycol (see [24] and [61]).

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However, Josephson fails to teach the magnetic particles size ranges from 0.5 to 10 um (microns).

Rohr teaches using magnetic particles coated with a polymer coating as labels in assays. The magnetic particles have size range between 0.01 um to 100 um or 0.01 to 10 um (see col. 12, lines 55-65). Rohr also discusses that "as will be appreciated by those skilled in the art, the composition, shape, size and density of magnetically attractable material may vary widely and a label can be selected based upon such factors as the analyte of interest and the desired assay protocol" (see col. 12, line 65-col. 13, line 2). Rohr further suggests that "the magnetic particles can be selected to have a specific gravity so as to tend to be suspended within the reaction mixture thereby enhancing the reactivity of the binding member. The magnetic particles can also be selected to have a specific gravity so as to tend to settle in the reaction mixture thereby enhancing the reactivity of the binding member with the immobilized reagent on the solid phase. (see col. 13, lines 3-25).

Thus, it would have been obvious to one of ordinary skills in the art to combine the teaching of Rohr and Josephson to use magnetic particles size ranges from 0.5 to 10 um because particles of this size do not settle rapidly in solution as those larger than 10 um nor do they require thermal agitation as those of size smaller than 0.5 um. (see Rohr col. 13, lines 3-25). One of ordinary skills in the art would have expected reasonable success in combining these two references because both references teach magnetic particles with polymer coating for use as labels in assays.

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However, Josephson and Rohr fail to teach using a polyalkylene glycol having 50 to 500 repeat units.

Thompson teaches using a polymer such as Polyethylene glycol (PEG) as a spacer, i.e. "if two groups are linked to the polymer such as PEG, one at each end, the length of the polymer can impact upon the effective distance, and other spatial relationships, between the two groups. The polymeric portion can be of any length or molecular weight but these characteristics can affect the biological properties. Polymer average molecular weights particularly useful for decreasing clearance rates in pharmaceutical applications are in the range of 200 to 35,000 daltons. If the polymer is a straight chain PEG, particularly useful lengths of polymers, represented by (Z)_n, where Z is the monomeric unit of the polymer, include n having a range of 50-500". (See [0075]).

Since Josephson teaches using PEG as a spacer and Thompson also uses PEG as a spacer, it would have been obvious to one of ordinary skills in the art to vary the length of the PEG in Josephson to have a range of monomers from 50-500 as taught by Thompson because Thompson teaches one can vary the length of the PEG within this range of monomers to optimize or confer the desired biological activity of the two groups being linked by the PEG.

For claims 2-4, 9 Josephson teaches that polymer is polyethylene glycol or polysaccharides and derivatives (see [24] and [61]).

For claim 6, Josephson teaches that the binding moieties are antibodies and the target analytes are antigen (see [78]).

For claim 8, Josephson teaches a method of detecting a target comprising contacting such composition described above with a sample and the magnetic resonance (magnetic signal) is detected. (see [83] and [84]). Josephson teaches immobilizing polymer such as polysaccharide to the particles via biotin-avidin complex. In this embodiment, the polysaccharide has reactive ends which are biotinylated and then is exposed to avidin linked nanoparticles (see [119], [130]). Josephson also teaches a step of washing the unbound specific binding material. (see [96] and [141]).

Claim 5, 7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Josephson et al. (US PGPub. 2003/0092029 A1) and further in view of Rohr and Thompson, as applied to claim 1-4, 6 and 8, and in view of Foster (US 4,444,879).

Josephson and Rohr and Thompson have been discussed above.

However, they fail to teach that the polyethylene glycol is bound to the magnetic particle via a biotin-avidin complex and packaging the composition described above into a kit.

Foster teaches packing assay reagents into a kit with instruction. (see col. 15, fig. 6).

For claims 5 and 10, although Josephson does not explicitly teaches attaching polyethylene glycol to the surface of a magnetic particles via biotin-avidin complex, Josephson teaches a method of immobilizing a polysaccharide to a nanoparticle, such

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polysaccharide is used the same way as the polyethylene glycol, as a spacer or linker to bind the binding moiety to the nanoparticle. (see discussion above). Thus, one of ordinary skills in the art would be motivated to immobilize the polyethylene glycol to the nanoparticle via a biotin-avidin complex as the polysaccharide.

For claim 7, it would have been obvious to one of ordinary skills in the art to pack the reagents used in the assay taught by Josephson combined with Rohr into a kit as taught by Foster for advantage of economic convenience and long-term storage.

Response to Arguments

Applicant's arguments filed September 20, 2010 have been fully considered but they are not persuasive.

Applicants cited the present specification to prove that the average molecular weight of the polyalkylene glycol is related to its length as a distinction over the cited references.

This is not found persuasive because:

It is irrelevant since the present claims do not recite any length or average molecular weight of the polyalkylene glycol.

Applicants further argue unexpected results by citing example 3 of the present specification illustrating the results between a PEG-antibody 1 and a PEG-antibody 2 wherein the PEG has a lower molecular weight. The PEG-antibody 1 draws out more antigen than the PEG-antibody 2. Applicants then conclude that since Josephson '029 does not disclose a "polyalkylene glycol having 50-500 repeat units", the PEG-antibody

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2 strongly evidences that the cited references do not produce the results of the present invention because the criticality of a polyalkylene glycol having 50-500 repeat units' has been proven.

This is not found persuasive because:

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Josephson is applied in combination with Rohr and Thompson. Although Josephson fails to teach that "the polyalkylene glycol having 50-500 repeat units", Thompson does remedy for such missing limitation. Thompson teaches using polyalkylene glycol having 50-500 repeat units and the molecular weight is in the range of 2000 to 35,000 daltons which covers the range of the molecular weight of 2200-22000 in the present specification. Therefore, the unexpected result argument is not found persuasive.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Pensee T. Do/
Examiner, Art Unit 1641

/Jacob Cheu/
Primary Examiner, Art Unit 1641